FOOD AND DRUG ADMINISTRATION (FDA)

Center for Drug Evaluation and Research (CDER)

Joint Meeting of the Anesthetic and Life Support Drugs Advisory Committee (ALSDAC) and Drug Safety & Risk Management Advisory Committee (DSaRM)

Holiday Inn, the Ballrooms, Two Montgomery Village Avenue, Gaithersburg, Maryland

September 24, 2009

AGENDA

The committees will discuss the resubmission of new drug application 22-272, OxyContin (oxycodone hydrochloride controlled-release) Tablets, Purdue Pharma L.P., and its safety for the proposed indication of management of moderate to severe pain when a continuous, around-the-clock analgesic is needed for an extended period of time. The controlled-release characteristics of this formulation are purportedly less easily defeated than other approved formulations of controlled-release oxycodone.

9:15 a.m.	Call to Order Introduction of Committee	**Jeffrey R. Kirsch, M.D.** Acting Chair, ALSDAC
	Conflict of Interest Statement	**Kalyani Bhatt** Designated Federal Officer, ALSDAC
9:25 a.m.	Opening Remarks	Clinical Team Leader, Division of Anesthesia, Analgesia, & Rheumatology Products (DAARP) CDER, FDA
FDA Presentations		
9:30 a.m.	History of OxyContin	Medical Officer, DAARP CDER, FDA
9:50 a.m.	Epidemiological Findings of Drug Misuse/Abuse In the United States: OxyContin	Epidemiologist Division of Epidemiology Office of Surveillance and Epidemiology CDER, FDA
10:10 a.m.	**Break**	
10:25 a.m.	**Sponsor Presentation**	**Purdue Pharma L.P.**
12:00 noon	**Lunch**	
1:00 p.m.	Open Public Hearing	
2:00 p.m.	Questions for the Presenters	
2:15 p.m.	**Break**	
2:30 p.m.	Discussion and Questions to the Committee	
4:30 p.m.	**Adjourn**	